

Serial No. 09/873,431

KOLTER et al.

PF 0000051497

R E M A R K S

It is respectfully requested that the Examiner enter and consider Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 as set forth in Appendix I of this paper. The claims differ from claims as previously before the Examiner in that Claims 10, 11, 14, 15, have been rewritten as new Claims 27 to 32, Claim 26 has been canceled, Claims 1, 8, 16, 17 and 20 have been amended to address the issues which were maintained by the Examiner, and new Claim 33 has been added to bring out an embodiment of the dosage form defined in Claim 17.

More particularly, applicants have made some editorial changes in Claims 1, 8, 16, 17, and 20. Additionally, applicants have further specified the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone in Claims 1 and 17 to bring out that the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate as disclosed on page 8, indicated lines 45 and 46, of the application. Applicants have also further specified the process step in Claim 1 to bring out that the granulation of the mixture of ingredients is conducted in the absence of solvents as disclosed on page 11, indicated lines 19 and 20, of the application, and new Claim 33 has been added to bring out the embodiment of the dosage form defined in Claim 17 which has an increased surface moisture as disclosed on page 6, indicated lines 1 and 2, of the application. No new matter has been added.

The Examiner indicated that the rejection under the judicially created doctrine of obviousness-type double patenting was withdrawn because applicants had submitted a Terminal Disclaimer. Upon review of the papers, applicants noted that the Terminal Disclaimer forwarded on August 10, 2004, erroneously referenced U.S. patent No. 4,837,032 instead of U.S. Patent No. 6,635,279 which was applied by the Examiner in the obviousness-type double patenting rejection. Applicants therefore herewith enclose a new Terminal Disclaimer which refers to U.S. Patent No. 6,635,279. Entry and consideration of the attached is respectfully solicited.

The Examiner criticized that Claim 15 contained the phrase "such as", and that Claims 14, 16 and 20 failed to use proper Markush language. Applicants have amended Claims 16 and 20 accordingly, and have rewritten Claims 14 and 15 as new Claims 29 to 32 to place them

050307

- 2 -

Serial No. 09/873,431

KOLTER et al.

PF 0000051497

in proper form. The wording of Claims 16, 20 and 29 to 32 should therefore now be proper.

The Examiner rejected Claim 26 under 35 U.S.C. §112, ¶2, and applicants have canceled that claim. Withdrawal of the respective rejection is therefore respectfully solicited.

The Examiner rejected Claims 17 to 23 and 25 under 35 U.S.C. §102(b) as being anticipated by the teaching of *Ortega* (US 4,837,032). The Examiner emphasized in this context that applicants could not rely on the argument that the polyvinylpyrrolidone was finely dispersed in the polyvinyl acetate because the respective feature, although supported by the application disclosure, was not specifically set forth in the claims. The revised version of Claim 17 which is herewith presented by applicants specifically sets forth in the definition of (a) that the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate in the formulated mixture of polyvinylpyrrolidone and polyvinyl acetate. The Examiner's argument why Claim 17 was deemed to be anticipated by the teaching of *Ortega* is therefore no longer applicable.

The Examiner also stated that it was not clear how a physical mixture of polyvinylpyrrolidone and polyvinyl acetate as addressed by *Ortega* was distinguished from a dispersion of polyvinylpyrrolidone in polyvinyl acetate as is now referenced in Claim 17. It is respectfully submitted that the "physical mixture" of polyvinylpyrrolidone and polyvinyl acetate which is addressed by *Ortega* comprises polyvinylpyrrolidone and polyvinyl acetate in form of individual and physically separate particles. In contrast to the individual and physically separate particles of the two polymers which is addressed by *Ortega*, the dispersion of polyvinylpyrrolidone in polyvinyl acetate which is referenced in applicants' claims provides that polyvinylpyrrolidone in finely divided form is evenly distributed throughout the polyvinyl acetate so that the composition of all particles is essentially the same. The fact that the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate in accordance with applicants' invention is, however, not intended to imply that polyvinylpyrrolidone and polyvinyl acetate react with one another.

In light of the foregoing and the attached it is respectfully requested that the rejection of Claims 17 to 23 and 25 under Section

050307

- 3 -

Serial No. 09/873,431

KOLTER et al.

PF 0000051497

REMARKS

102(a) be withdrawn. Claim 33 depends upon Claim 17 and the subject matter of Claim 17 is, therefore, also not anticipated by the teaching of *Ortega*. Favorable action is solicited.

The Examiner rejected Claims 1 to 7 and 9 to 16 (now: Claims 1 to 9, 12, 13, 16 and 27 to 32) under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Ortega* (*ibid.*). In this context, the Examiner took the position that applicants' earlier argument that the claimed process differed from the process addressed by *Ortega* because applicants' granulation step was not a wet granulation was not persuasive because the claims failed to exclude the wet granulation which is taught by *Ortega*.

Applicants have further specified the granulation stage to bring out that the granulation is conducted in the absence of a solvent. Accordingly, the wet granulation which is conducted by *Ortega* to obtain the particles can no longer be deemed to fall within the realm of applicants' granulation stage. It is therefore respectfully requested that the rejection of Claims 1 to 7 and 9 to 16 (now: Claims 1 to 9, 12, 13, 16 and 27 to 32) under Section 103(a) be withdrawn. Favorable action is solicited.

For essentially the same reasons it is respectfully requested that the rejection of Claims 1 and 8 under 35 U.S.C. §103(a) based on the teaching of *Ortega* (*ibid.*) when taken in view of the disclosure of *Noda et al.* (US 5,389,380) be withdrawn. The Examiner relied upon the disclosure of *Noda et al.* essentially for its showing that theophylline can be combined with lactose or starch or mannitol. Neither the respective showing of *Noda et al.* nor any other part of the disclosure of *Noda et al.* is, however, suitable to close -or even narrow- the gap between the wet granulation process which is taught by *Ortega* and the "dry" granulation process which is employed in accordance with applicants' invention. Favorable action is solicited.

In light of the foregoing and the attached, the claims herewith presented by applicants are deemed to be patentable under the provisions of Sections 102, 103 and 112, and the application should now be in condition for allowance. Early action by the Examiner is respectfully solicited.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit

050307

- 4 -

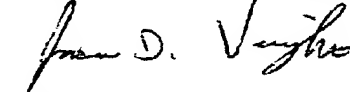
Serial No. 09/873,431

KOLTER et al.

PF 0000051497

Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,  
NOVAK DRUCE DELUCA & QUIGG



Jason D. Voight  
Reg. No. 42,205

1300 Eye Street, N.W.  
Suite 400 East  
Washington, D.C. 20005  
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)  
Terminal Disclaimer concerning U.S. Patent No. 6,635,279  
Petition under 37 C.F.R. §1.181

JDV/BAS

050307

- 5 -